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Social cognitive group treatment for impaired insight in psychosis: A multicenter randomized controlled trial☆

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ABSTRACT

Purpose: The majority of people with schizophrenia has impaired insight, which is related to a poorer outcome. In this study, we evaluate a new psychosocial intervention 'REFLEX' aimed at improving insight in people with schizophrenia. REFLEX focuses on targeting stigma-sensitivity, perspective taking and self-reflection in people with schizophrenia and low insight. Primary objective is to improve insight and subsequently to improve functional outcome and symptoms.
Method: A total of 121 people diagnosed with schizophrenia according to DSM IV criteria with impaired insight was included in 2012–2015 from seven sites in a multicenter randomized controlled trial. REFLEX was compared to an active control condition consisting of group-wise simplified cognitive remediation training. Primary outcome of the study were the preconditions of insight: internalized stigma, self-reflection, mental flexibility and perspective taking. Clinical insight and cognitive insight were secondary outcomes.
Results: Although perspective taking, self-reflection, mental flexibility and stigma sensitivity remained unchanged after the intervention, results showed a significant improvement of clinical insight in both conditions directly after treatment (SAI-E Rater, $p < .001$, PANSS G12, $p < .005$) and at follow-up (SAI-E Rater, $p < .01$, SAI-E interview, $p < .001$, PANSS G12, $p < .0001$). Improvement of clinical insight directly after treatment was larger in the REFLEX condition (SAI-E Rater, $p < .05$). Other outcomes (self-esteem, quality of life and depression) remained unchanged.
Conclusion: Though insight improved in both conditions, REFLEX was not superior to simplified drill-and-practice cognitive remediation training. Nevertheless, this study indicates that structured interventions can significantly improve insight. Further research on the underlying mechanisms of both conditions is needed, as insight is unlikely to improve spontaneously in chronic patients.

1. Introduction

Many individuals with schizophrenia show a striking lack of insight into their condition (Dam, 2006). Poor insight has negative associations with many relevant outcomes of schizophrenia such as self-esteem, mood and quality of life (Stefanopoulou et al., 2009; Drake et al., 2007; Lincoln et al., 2007), making insight an important target for treatment.

Evidence suggests that treatment with antipsychotic drugs leads to increased insight, although this effect may be limited to the early phase of treatment (Pijnenborg et al., 2015). Alternatively, though insight may be increased through psychosocial interventions, substantial improvement of treatment options remains (Pijnenborg et al., 2013). For example, cognitive behavioral therapy, psycho-education and adherence therapy did not significantly improve insight in the small trials that have been conducted to date. Preliminary evidence does exist for a comprehensive intervention aiming to decrease self-stigma that improved insight (Fung et al., 2011). Integrating such approaches into

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one targeted cognitive-behavioral treatment aimed at increasing insight may thus be effective.

In this study, a new theory-driven intervention aiming to increase clinical insight in schizophrenia was evaluated. The intervention (REFLEX) was based on an integrative model of insight (Fig. 1) that summarizes factors contributing to poor clinical insight in psychotic disorders (Pijnenborg et al., 2011). Clinical insight has been distinguished from cognitive insight and refers to the awareness of having a mental illness, being able to recognize the symptoms thereof and recognizing the need for treatment (David, 1990). Cognitive insight involves patients' ability to evaluate or distance themselves from anomalous experiences and erroneous inferences (Beck et al., 2004) and is conceptualized as a combination of self-reflection and self-certainty. Although literature on the relationship between cognitive insight and clinical insight is inconsistent (David et al., 2012), hypo-activation in brain areas traditionally associated with self-reflection was found in relation to both poor clinical and poor cognitive insight (Van Der Meer et al., 2013).

This suggests that self-reflection is highly relevant for both clinical and cognitive insight (Van der Meer et al., 2012). Therefore, the association between self-reflection and insight is central to the model: poor insight is considered the outcome of impaired self-reflection. Self-reflection is thought to mediate the relationship between impaired insight and factors that have been proposed as preconditions of poor insight: perspective taking (Langdon and Ward, 2009), stigma sensitivity (Cooke et al., 2005; Lysaker et al., 2005) and neurocognition (Mintz et al., 2003). Neurocognitive deficits may limit a patient's ability to consider alternative viewpoints and the integration of outside information. This may in turn limit the patient's ability to understand that he or she has an illness (Riggs et al., 2012) and may lead to an inability to incorporate mental health problems into a personal narrative (Buck et al., 2009). Especially Theory of Mind was found to be associated with insight; being able to see the world from the perspective of others is associated with a better understanding of one's own mind (Pijnenborg et al., 2013; Vohs et al., 2016).

Importantly, a factor that needs to be considered in the development of an intervention aiming at increasing insight is self-stigma (Belvederi et al., 2015). Patients with poor insight often show poorer social functioning, are less adherent and have more symptoms, while patients with good insight are more often depressed and report lower quality of life (Olfson et al., 2006; Francis and Penn, 2001; Kvrgic et al., 2013; Hasson-Ohayon et al., 2006; Hasson-Ohayon et al., 2009). This phenomenon is known as the insight paradox (Lysaker et al., 2007) with evidence suggesting that its self-stigma moderates the relationship between insight and outcomes (Lysaker et al., 2007). People with high self-stigma tend to get more depressed when insight is better.

In sum, REFLEX aims to improve insight by targeting self-reflection, perspective taking and stigma-sensitivity. During the intervention people are encouraged to reconstruct their own personal narrative, including their mental health problems (Lysaker et al., 2010). Because of the mediation effect of self-stigma, stigma sensitivity is an additional target in the intervention.

1.1. Aims of the study

The aim of this study was to evaluate the effectiveness of REFLEX as an intervention for improving insight in people with schizophrenia. REFLEX was compared to an active control condition consisting of group-wise simplified drill-and-practice cognitive remediation training (simplified CRT). The primary objective was to improve clinical insight by stimulating its preconditions. Given their associations with insight, we expected mood, self-esteem and quality of life to improve as well.

2. Experimental/materials and methods

2.1. Subjects

A total number of 121 patients were recruited in seven mental health care centers in the Netherlands (see Table 1 for demographic and clinical variables). Inclusion criteria were: 1) having a diagnosis of schizophrenia established by the Mini International Neuropsychiatric Interview-Plus 5.0.0. (MINI-Plus; Sheenan et al., 1998), a semi-structured interview to assess DSM-IV pathology; 2) having impaired insight, indicated by a score of ≤9 on the Psychosis Inventory (Birchwood et al., 1994) and established by a clinician's rating defined as one or more non-affirmative answers on three questions assessing awareness of mental illness, recognition of symptoms and acknowledging need for treatment. In case of an inconsistency between these two, a Positive and Negative Syndrome Scale interview (PANSS; Kay et al., 1987) was administered. Patients with scoring >3 on item G12 (meaning at least a mild degree of impaired insight) were considered eligible for the trial; 3) age > 18 and 4) being able to give informed consent. Exclusion criteria were 1) receiving cognitive behavioral therapy 2) an acute episode of psychosis 3) a co-morbid neurological disorder. All patients received treatment as usual (TAU) in addition to REFLEX or CRT, according to Dutch clinical guidelines that are in line with the international NICE guidelines.

2.2. Procedure

Potentially eligible patients were referred by their treating clinicians. Study procedures were explained and patients were given a reflection

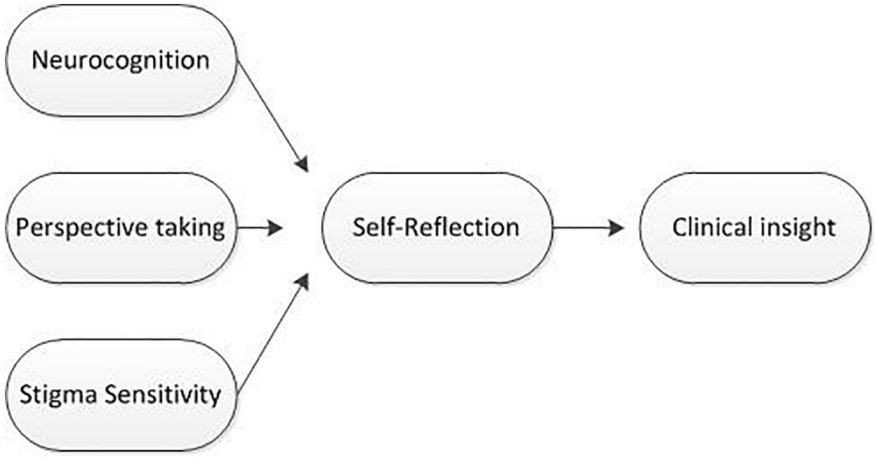

Fig. 1. Preconditions of insight.

Table 1
Baseline demographic and disease variables of all randomized 121 patients per condition.

	Control (n = 62)	REFLEX (n = 59)
Age (mean, Sd)	38.55 (12.66)	40.82 (10.81)
Gender (% men)	87.1*	70.0
Level of education (mean, Sd)	5.13 (1.22)	4.97 (1.16)
Number of psychotic episodes (mean, Sd)	3.68 (4.04) Chronic psychotic symptoms: n = 3	4.15 (4.80) Chronic psychotic symptoms: n = 4
Years of illness (mean, Sd)	11.32 (9.12)	14.06 (10.39)
Baseline PANSS pos (mean, Sd)	15.70 (4.42)	15.88 (4.40)
Baseline PANSS neg (mean, Sd)	14.63 (5.29)	14.54 (5.10)
Baseline PANSS gen (mean, Sd)	32.25 (7.91)	32.17 (6.17)
Antipsychotic medication (%, n)		
Dipiperon	0% (0)	1.7% (1)
Olanzapine	14.5% (9)	36.7% (21)
Clozapine	33.9% (21)	30% (17)
Paliperidon	1.6% (1)	3.4% (2)
Risperidon	20.8% (13)	8.5% (5)
Quetiapine	4.8% (3)	11.9% (7)
Pimozide	1.6% (1)	0% (0)
Aripiprazol	11.2% (7)	10.2% (6)
Cisordinol	1.6% (1)	6.8% (4)
Haloperidol	4.8% (3)	5.1% (3)
Bromperidol	0% (0)	1.7% (1)
Anti-depressants	14.5% (9)	10.2% (6)
Mood-stabilizers	9.6% (6)	5.1% (3)
Tranquilizers	30.6% (19)	22.0% (13)
Inpatient	9.7% (6)	10.2% (6)
Outpatient	62.9% (39)	66.1% (39)
Sheltered housing	27.4% (17)	23.7% (14)
Clinical insight (mean, Sd)		
SAI-E interview	11.84 (4.4)	11.50 (4.9)
SAI-E clinician	6.22 (2.5)*	7.31 (2.2)
PANSS G-12	3.81 (1.2)	3.81 (1.1)
Cognitive insight/self-reflection (mean, Sd)		
BCIS self-reflectiveness	23.85 (3.6)*	21.8 (4.1)
BCIS self-certainty	14.60 (3.3)	14.15 (2.9)
S-RIS total	72.42 (10.1)	71.95 (9.3)
BCIS cognitive insight	6.26 (4.7)*	4.68 (5.3)
Perspective taking (mean, Sd)		
DACOBS (ToM)	23.92 (5.3)	24.0 (5.6).
Self-stigma (mean, Sd)		
ISMI total	63.52 (17.4)	61.95 (9.9)
Depression (mean, Sd)		
QUID-Sr	3.84 (1.8)	4.14 (1.7)
Self-esteem (mean, Sd)		
SERS pos	46.21 (10.4)	47.37 (10.6)
SERS neg	31.08 (10.9)	32.22 (10.8)
Quality of life (mean, Sd)		
MANSA	58.13 (9.9)	58.17 (9.2)
Symptoms (mean, Sd)		
PANSS pos	18.74 (6.2)	18.16 (5.2)
PANSS neg	12.94 (5.8)	12.31 (5.3)
PANSS des	21.69 (6.7)	22.17 (5.9)
PANSS exc	12.87 (3.8)	12.80 (3.2)
PANSS emo	16.60 (4.9)	16.45 (3.9)

A scale (Verhage, 1964) ranging from 1 = primary school (6 years of formal education) to 7 = university (16 years of formal education).
* $p < .05$.

period of two weeks after which written informed consent was obtained. Subsequently, diagnosis was verified by the researchers with the Mini Plus. Randomization procedures were started when the optimal number of patients per center (ranging from 17 to 19) was included, or, when the first patient was included more than six weeks ago, while >10 people were included.

All patients were assessed at baseline (T0), directly post-treatment (T1) and six months post-treatment (T2) by trained research assistants, blind to randomization status. Treatment fidelity was monitored after training session. The trial complied with the declaration of Helsinki, was approved by the Institutional Review Board of the UMCG and registered in the trial register 'current controlled trials' (ISRCTN50247539).

2.3. Materials

2.3.1. Intervention

2.3.1.1. REFLEX. REFLEX encompasses three modules of four one-hour group sessions each. Module I "Coping with Stigma" focuses on coping with stigmatizing beliefs. The impact of stigmatizing beliefs is discussed and stigmatizing beliefs are disputed and replaced with functional reality-based beliefs about the self. Patients learn that a diagnosis is just a label, saying little about them. The goal of this module is twofold: first, we presume that denial to cope with the threat that mental illness poses on the self-esteem will be less necessary when the idea of having a mental illness is perceived as less threatening. Following this train of thought, challenging stigmatizing beliefs will ultimately contribute to better insight. Second, with the inclusion of the stigma module we want to prevent an increase of depression to co-occur with increasing insight, as literature has shown that stigma mediates the relationship between insight and mood. In the module "You and your personal narrative" self-reflection is the central theme. Subjects reconstruct their personal narrative, reflect on important changes in their lives and their personal strengths and weaknesses. By offering very structured exercises with clear instructions, REFLEX compensates for cognitive impairments that are thought to hamper self-reflection in schizophrenia. In this module, subjects start practising perspective-taking. Subjects are instructed to ask themselves on a regular basis what other people would think about their thoughts and to check this with an important other. In the third module, called "You in the present", reflection about ongoing thoughts and feelings is stimulated. Between sessions, subjects monitor their thoughts and feelings in their daily life by experience-sampling (Myin-Germeys et al., 2009). In response to a random signal (beeping of a watch) provided six times a day, patients write down the answer to a fixed number of short questions that stimulate self-reflection in a diary. Examples of these questions are: "what was I thinking about before the alarm went off?" and "what would other people think about this thought?". During group sessions, the content of these dairies is discussed. In addition, group exercises and movie vignettes are used to practice perspective-taking during treatment sessions.

2.4. Control condition

The protocolized control condition consists of twelve one-hour group sessions of standardized 'drill-and-practice' exercises. Instructions were provided by master students in psychology. Most 'pen-and-paper' exercises were adopted from Cognitive Remediation Training protocol (Delahunty and Morice, 1996). Exercises explicitly stimulating mental flexibility were removed, as these showed a relationship with insight in psychoses in a meta-analysis (Aleman et al., 2006). To prevent participants from gaining more insight in their own performance, trainers did not provide any feedback.

2.4.1. Instruments

2.4.1.1. Screening. Psychosis Insight Scale (*PI,* Birchwood et al., 1994): an eight item self-report questionnaire, consisting of three subscales: awareness of illness; relabeling symptoms to illness, and need for treatment.

2.4.1.2. Classification. MINI-plus (Sheenan et al., 1998): a structured interview to asses axis I disorders according to DSM IV and ICD 10 criteria.

2.4.1.3. Preconditions of insight (primary outcomes).

Stigma sensitivity:

The Internalized Stigma of Mental Illness Scale (*ISMI;* Ritscher et al., 2003): a self-rating questionnaire measuring the subjective experience of stigma (29 Likert-scale items).

Self-reflection:

The Self-Reflection and Insight Scale (*S-RIS;* Grant et al., 2002): a self-rating questionnaire measuring 'Need for self-reflection', 'Engagement in Self-reflection' and 'Insight' (20 Likert-scale items).

Subscales of the Beck Cognitive Insight Scale (*BCIS;* Beck et al., 2004): a self-rating questionnaire evaluating patients' self-reflectiveness and idiosyncratic self-certainty. The scale consists of 15-items, divided into two subscales: self- reflectiveness (9 items) and self-certainty (6 items).

Perspective-taking:

The Theory of Mind subscale of the *Davos Assessment of Cognitive Biases Scale* (*DACOBS;* Van der Gaag et al., 2013): 42-item Likert self-rating scale that measures cognitive biases and safety behavior in psychosis. The social cognitive problems subscale was used to assess perspective-taking.

2.4.1.4. Clinical insight and cognitive insight (secondary outcomes). Schedule for Assessment of Insight-Expanded (*SAI-E;* Amador et al., 1993): a 12-item semi-structured interview to assess insight, based on David's three dimensions of insight. The SAI-E takes both the opinion of the interviewer and the clinician into account. The SAI-E was divided into two variables: SAI-E Interview (questions 1–9) and SAI-E Rater (questions A, B and C).

Item G12 of PANSS (Kay et al., 1987): Item G12 of the PANSS assesses insight in psychosis and is highly correlated with other insight measures, such as the SAI, SAI-E and ITAQ.

The Beck Cognitive Insight Scale (*BCIS;* Beck et al., 2004): a self-rating questionnaire evaluating patients' self-reflectiveness and idiosyncratic self-certainty. The scale consists of 15-items, divided into two subscales: self- reflectiveness (9 items) and self-certainty (6 items). The delta of this items represents cognitive stigma.

2.4.1.5. Other outcome measures. Depression:

The *Quick Inventory of Depressive Symptomatology Self-Report* (*QIDS-SR;* Rush et al., 2003) is a 16-item self-report questionnaire that rates depressive symptoms according to the DSM-IV in the week before assessment. The *QIDS-SR* has been validated for patients with schizophrenia (Ma et al., 2015).

Self-esteem:

The *Self-Esteem Rating Scale-Short Form* (Lecomte et al., 2006) is a self-report questionnaire measuring self-esteem encompassing statements linked to social contacts, achievement and competency and validated for people with schizophrenia. The SERS has two 10-item subscales: positive and negative self-esteem.

Quality of Life:

The *self-rating Manchester Short Assessment of Quality of Life* (*MANSA;* Priebe et al., 1999): The MANSA is a self-report questionnaire containing four objective questions and twelve subjective questions on satisfaction with life as a whole (16 Likert-scale items).

Symptoms:

Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987). This semi-structured interview was employed by trained raters to indicate the severity of 30 symptoms of psychosis on five scales (Van der Gaag et al., 2006): positive symptoms, negative symptoms, disorganization, excitement, and emotional distress using a seven-point Likert scale, ranging from 'Absent' to 'Extreme'.

Unless indicated otherwise, total scores are used in the analyses.

2.5. Statistical analyses

To examine whether randomization was successful, differences in baseline demographical and disease variables were tested. A X^{2-}tests was applied for gender, and independent sample *t*-test with condition as independent variable were applied to test for differences in age, level of education, duration of illness, living situation/treatment type and PANSS total respectively. Tests were two-tailed, with significance levels set at $p < .05$. Variables that significantly differed between conditions were entered as covariates in subsequent analyses.

To compare the effects of REFLEX on the study's outcomes, multilevel modeling was applied. MLwinN (Rasbash et al., 2005) was used to build a 2-level model for each of the dependent variables, where subjects were modelled at level 2 and time of assessment at level 1. Fixed predictors were: a) intercept and dummy variables representing time (T0, T1, T2); b) condition; c) the interaction term time*condition. As random effects, we included the random intercept at level 2 and the residual variance at level 1. Statistical significance of fixed effects were tested using the approximate *t*-test, and of random effects using the deviance test, with a significance level set at $p < .05$. First, an intention to treat (ITT) analysis on the entire sample was performed. Subsequently, we performed a sensitivity analysis including only participants who attended more than six group sessions (>50% of the training). Finally, to examine the effects of REFLEX on insight over and above that of an overall symptom-level at each measurement occasion, the overall symptom-level except insight was included (PANSS minus item G12).

3. Results

Of the demographic and disease variables, only gender differed significantly between groups at baseline, with significantly more men in the control condition (X^2 df = 1, 5.32, $p < .05$, see Table 1), thus gender was entered as a covariate in further analyses. Drop-out rates were comparable between conditions (see Fig. 2 for a detailed flow chart of all inclusions and drop-outs).

There was a significant difference in the number of sessions patients attended ($t = 2.14$, df = 119, $p < .05$, 95% c.i. 0.12–3.07): the mean number of sessions in the control group was 7.31 (Sd 4.6), and in the REFLEX condition 8.90 (Sd 3.5).

3.1. Randomization

Patients in the control condition had significantly lower clinician rated insight at baseline ($t = 2.20$, df = 109, $p < .05$) and scored significantly higher on BCIS self-reflection and BCIS cognitive insight at baseline ($t = 3.26$, df = 115, $p < .001$; $t = 2.67$, df = 115, $p < .01$). There were no other baseline differences (see Table 1).

3.2. Intention to treat analyses

3.2.1. Preconditions of insight: cognitive insight/self-reflection/perspective taking/self-stigma

There was no significant increase of cognitive insight/self-reflection (BCIS self-reflection/BCIS self-certainty/S-RIS total), and social cognition (DACOBS) in either condition between baseline and post-treatment (BCIS self-reflection: $t = 0.99$, df = 115, n.s.; BCIS self-certainty: $t = 0.71$, df = 115, n.s.; S-RIS total: $t = 0.40$, df = 115, n.s.; DACOBS social cognitive problems: $t = 0.58$, df = 115, n.s.) or between baseline and follow-up (BCIS self-reflection: $t = 0.99$, df = 115, n.s.; BCIS self-certainty: $t = 0.36$, df = 115, n.s.; S-RIS total: $t = 0.76$, df = 115, n.s.,

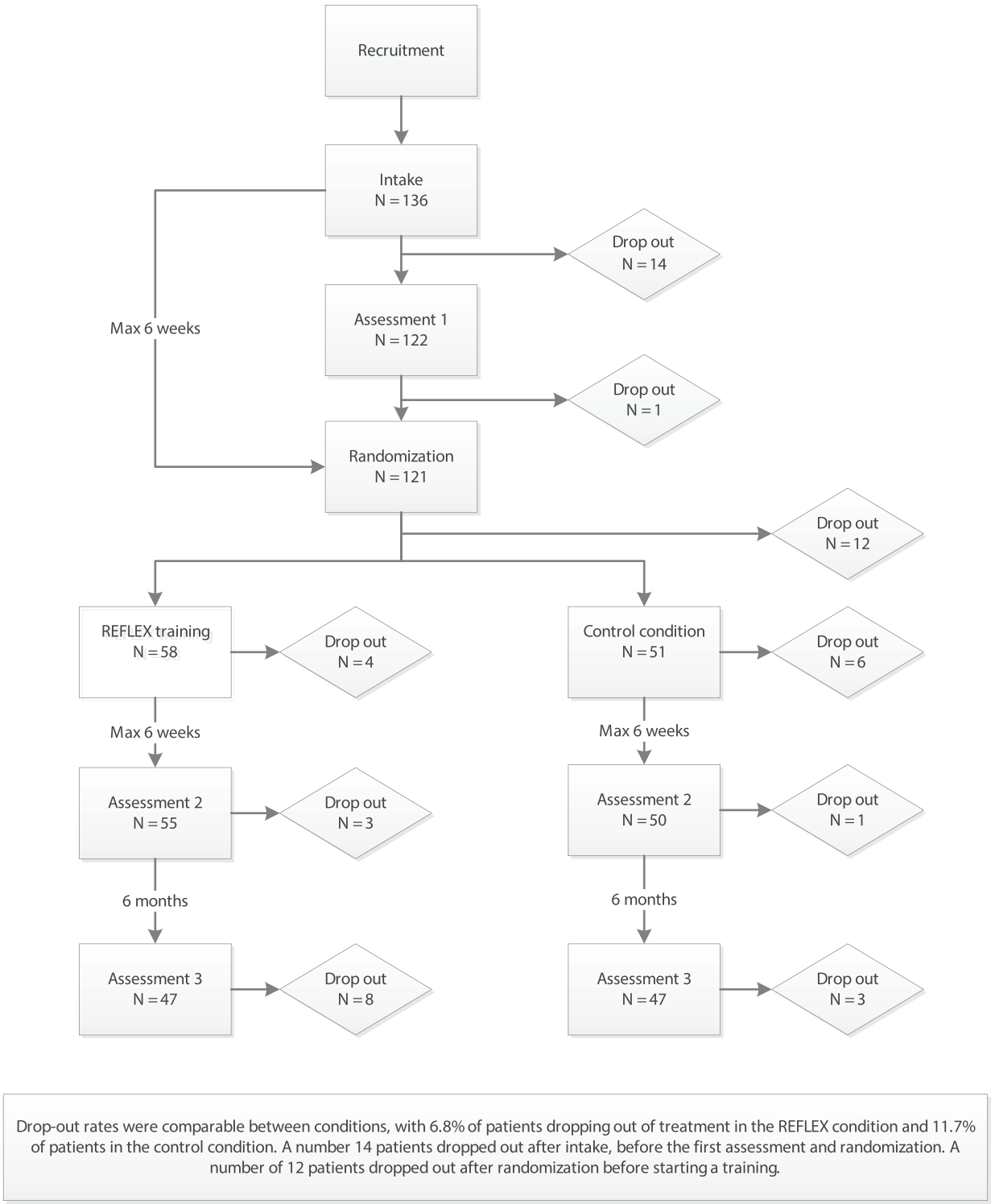

Fig. 2. Flow chart. 6.8% dropped out of the REFLEX condition and 11.7% of the control condition.

see Table 2 for means and Sd). Perspective taking increased significantly between baseline and follow-up over both conditions (DACOBS social cognitive problems $t = 3.01$, $df = 115$, $p < .005$). Self-stigma showed a small, non-significant decrease post-treatment (ISMI baseline-post-treatment: $t = 1.48$, $df = 115$, n.s.). While there was no significant overall difference between baseline-and follow-up ($t = 0.56$, $df = 115$, n.s.), self-stigma returned to baseline in the REFLEX condition but decreased significantly further in control condition (ISMI baseline-follow-up*condition $t = 1.94$, $df = 115$, $p < .05$).

3.2.2. Insight

3.2.2.1. Clinical insight. Clinical insight improved significantly in both conditions (see Fig. 3 and Table 2 for statistical details). Clinical insight assessed with SAI-E Rater and PANSS-G12 was significantly better post-treatment than at baseline and significantly better at follow-up than at baseline for all three clinical insight measures. Patients in the REFLEX condition improved significantly more than in the control condition on clinician-rated insight, this interaction effect disappeared at

Table 2
Post-training and follow-up assessment (intention to treat analyses).

		Post-training		Follow-up	
		Control	REFLEX	Control	REFLEX
Clinical insight (mean, Sd)	SAI-E interview	12.14 (5.5)	12.40 (6.2)	14.96 (5.4)	14.90 (5.2)
	SAI-E clinician	6.43 (3.0)	8.31 (2.4)	8.23 (2.5)	8.68 (2.3)
	PANSS G-12	3.18 (1.2)	3.31 (1.4)	2.74 (1.2)	2.71 (1.4)
Cognitive insight/self-reflection (mean, Sd)	BCIS self-reflectiveness	23.65 (4.4)	22.31 (3.9)	23.57 (4.5)	21.95 (3.5)
	BCIS self-certainty	14.04 (3.82)	14.37 (2.9)	13.88 (3.6)	13.60 (2.8)
	S-RIS total	73.0 (8.1)	72.83 (9.6)	70.27 (7.9)	71.36 (7.7)
	BCIS cognitive insight	6.56 (6.2)	5.01 (5.2)	6.53 (5.1)	5.01 (4.5)
Perspective taking (mean, Sd)	DACOBS (ToM)	23.61 (6.0)	22.78 (6.2)	22.17 (5.8)	23.19 (4.9)
Self-stigma (mean, Sd)	ISMI total	60.47 (8.5)	59.90 (9.8)	58.67 (9.7)	60.07 (9.6)
Depression (mean, Sd)	QUID-SR	3.68 (1.9)	3.71 (1.9)	3.62 (1.8)	4.02 (1.9)
Self-esteem (mean, Sd)	SERS pos	47.59 (11.1)	49.05 (10.9)	46.83 (11.1)	47.17 (9.3)
	SERS neg	29.6 (9.5)	30.65 (10.2)	28.86 (10.7)	31.74 (9.9)
Quality of life (mean, Sd)	MANSA	56.88 (10.7)	58.75 (9.3)	57.91 (10.3)	58.25 (9.8)
Symptoms (mean, Sd)	PANSS pos	16.22 (6.5)	15.67 (5.6)	16.02 (6.0)	14.23 (5.5)
	PANSS neg	11.84 (6.0)	11.47 (4.6)	10.87 (5.4)	11.23 (4.8)
	PANSS des	20.38 (6.1)	19.67 (5.9)	20.38 (6.2)	19.86 (6.1)
	PANSS exc	12.58 (4.3)	11.85 (3.0)	13.02 (4.9)	12.33 (3.3)
	PANSS emo	14.62 (4.7)	15.01 (4.6)	16.11 (5.1)	15.23 (4.9)

follow-up. Other interactions between time and condition were not significant.

3.2.2.2. Cognitive insight. Cognitive insight remained stable over time between baseline and post-treatment ($t = 0.99$, $df = 115$, n.s.) and between baseline en follow-up ($t = 0.60$, $df = 115$, n.s.).

3.2.2.3. Depression, self-esteem, symptoms and quality of life. Quality of life was increased post-treatment in both conditions (MANSA ($t = 3.05$, $df = 115$, $p < .01$). Self-esteem and depression remained stable over time, there were no significant differences between conditions (baseline-post-treatment: self-esteem: SERS-pos $t = 1.28$, $df = 115$, n.s.; SERS neg $t = 0.89$, $df = 115$, n.s.; depression: QUID-SR $t = 1.42$, $df = 115$, n.s; quality of life: MANSA $t = 0.72$, $df = 115$,n.s.; PANSSpos $t = 0.57$, $df = 115$, n.s.; PANSSneg $t = 0.34$, $df = 115$, n.s.; PANSSdes $t = 0.57$, $df = 115$, n.s.; PANSSemo $t = 0.75$, $df = 115$, n.s.; PANSSexc $t = 0.09$, $df = 115$, n.s.) and baseline-follow-up: self-esteem: SERS-pos $t = 0.16$, $df = 115$, n.s.; SERS neg $t = 0.09$, $df = 115$, n.s.; depression: QUID-SR $t = 0.30$, $df = 115$, n.s; quality of life: MANSA t.13, $df = 115$, n.s.; PANSSpos $t = 0.96$, $df = 115$, n.s.; PANSSneg $t = 0.32$, $df = 115$, n.s.; PANSSdes $t = 0.96$, $df = 115$, n.s.; PANSSemo $t = 0.38$, $df = 115$, n.s.; PANSSexc $t = 0.27$, $df = 115$, n.s.).

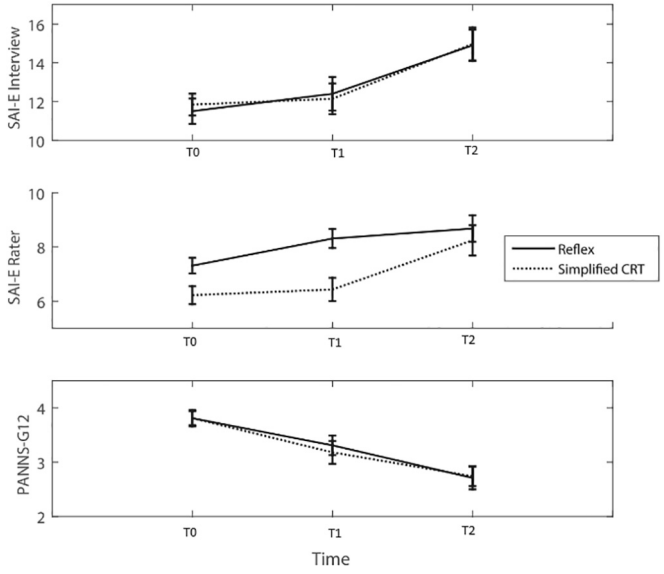

Fig. 3. Improvement of clinical insight over time per condition

3.3. Sensitivity analyses and controlling for overall symptom-level

Results of the sensitivity analyses did not change the implications of the results of the intention-to-treat analyses, nor did controlling for overall symptom level at each occasion (T0-T2).

4. Discussion

The main finding of this study is that both REFLEX and simplified CRT resulted in significantly improved clinical insight. Several studies have shown that while clinical insight improves with pharmacological treatment in the first phase of illness, it is relatively stable in non-recent onset patients receiving treatment as usual (Pijnenborg et al., 2013; Van Baars et al., 2013). Given that the large majority of the patients in this trial had been ill for several years, the improvement in insight we found in both conditions is not likely to be simply an effect of time. The fact that subjective quality of life improved significantly in both conditions refutes the idea that improving insight leads to low mood.

Our primary outcomes, the preconditions of insight, that were expected to mediate insight change, remained stable in both conditions. Although the mechanisms underlying changes need further research, REFLEX stimulated clinical insight. This has consequences for our model: changes in clinical insight are possible without changes in its preconditions. Possibly, specific elements of REFLEX, such as challenging dysfunctional beliefs about diagnostic labels and reflecting on the impact of symptoms in daily life have directly stimulated clinical insight. Although this is not necessarily evidence against a relationship between perspective taking, self-reflection, and stigma sensitivity with clinical insight, it may be that the supposed mediators are in fact more stable measures of personal style.

In contrast with our expectations, REFLEX did not decrease self-stigma. Baseline self-stigma was low, leaving little room for improvement. This may have been an effect of our recruitment strategy that was based on impaired insight: people with impaired insight report less self-stigma (Schrank et al., 2013). A meta-analysis on interventions that reduce self-stigma in mental illness had mixed results, probably due to methodological limitations of these studies and heterogeneity of the interventions and low statistical power of the meta (Büchter and Messer, 2017). Results for NECT, an intervention addressing self-stigma (Yanos et al., 2012) that was very comparable to REFLEX in combining psycho-education and cognitive restructuring with narrative enhancement (focusing on sharing and telling personal narratives about oneself and one's mental illness) were mixed, with the first study not showing a difference in insight and self-stigma between the intervention and

TAU, while a recent study on NECT in a larger sample did find an effect of the intervention on self-stigma (Hansson et al., 2017). Thus, it would be preliminary to conclude that narrative enhancement cannot decrease self-stigma. Another intervention focusing on identity enhancing is Photovoice (Russinova et al., 2014). Photovoice is a manualized peer-led intervention, in which photos and narratives corresponding to coping with psychiatric illnesses are discussed in a group. Moreover, psychoeducation on stigma is offered in combination with exercises aiming to strengthen identity. In contracts to REFLEX, Photovoice was effective in reducing self-stigma. Effective elements of Photovoice, compared to REFLEX, may have been the use of non-verbal material with a personal meaning or the interaction with peers.

Together with our own findings the conclusion that stimulating personal narratives does not lead to decreased self-stigma seems justified. When developing this study, we considered the active control condition a strength of the design, as it controls for "general" treatment effects. However, the active control condition may have had unexpected effects on insight. This could be due to a-specific elements that both interventions have in common. Alternatively, specific elements of CRT may lead to an increase of insight. Indeed a meta-analysis showed an association of clinical insight and basic cognitive skills (Nair et al., 2014). In line with this, a clinical trial (Lalova et al., 2013) that compared training of basic cognitive processes, autobiographical memory, and metacognitive functions showed that each of these interventions was associated with improved clinical insight. Since we did not expected REFLEX to have an effect on neurocognition, this was not included as an outcome. Therefore, we cannot definitely conclude that insight-change in the CRT condition was precluded by improved cognitive functioning. Alternatively, a-specific elements of both interventions, such as weekly peer-to-peer contact and working on structured assignments together with others with the same diagnosis, may have been responsible for increased insight. The significantly higher attendance rate for REFLEX over CRT may indicate that patients preferred this intervention.

REFLEX did not increase cognitive insight. This finding is in line with the effects of another study on the effects of a training focusing on social cognition in psychotic disorders on cognitive insight (Tas et al., 2012). Scores on the self-certainty subscale of the BCIS even decreased after this training. However, there was no effect of this training on the BCIS composite index, nor on the self-reflection subscale (Tas et al., 2012). Moreover, another recent clinical trial evaluating a self-reflection training for people with schizophrenia also failed to find an effect on cognitive insight (Jørgensen et al., 2014).

Recently, Vohs et al. (2016) published an integrative model of insight, that largely overlaps the model of insight on which REFLEX was based (Pijnenborg et al., 2011), and added meta-cognition as a predictor of poor self-reflectivity. Metacognition here refers to activities that allow people to be aware of and form complex representations of self and others and might be a target for psychotherapy.

Indeed, a metacognitive therapy (MERIT) for psychoses was found to have a positive effect on insight in a first episode sample (Vos et al., in press). MERIT stimulates metacognitive capacity defined as a spectrum of metacognitive activities that involve thinking about thinking, ranging from discrete acts, in which people recognize specific thoughts and feelings, to more synthetic acts, in which an array of intentions, thoughts and feelings and connections between events are integrated into larger complex representations (Lysaker et al., 2013). Perhaps focussing on these more integrative aspects of social processes is necessary to improve insight.

4.1. Limitations

This study has several limitations. First, insight was assessed as knowledge about one's mental health problems, or, in other words, as a relatively isolated set of cognitions. This operationalization of insight does not take in to account the fact that awareness of illness is an inextricable part of a personal narrative (Lysaker et al., 2010). It may be that assessing insight in a more narrative way would have been more sensitive to the specific effects of REFLEX. Second, self-reflection and perspective taking were assessed with self-report. This may have masked effects on these outcomes. Jørgensen et al. (2014) found that training self-reflection in psychotic disorders was even associated with a decrease in cognitive insight. May be increased insight leads to more realistic scores, i.c. most often lower scores on self-report. Third, in contrast with PANSS-raters, clinicians who completed the SAI-E items for clinicians were not blind, which may have influenced their scores.

5. Conclusion

Although REFLEX was composed to address specific aspects of insight, it's effects were not superior to that of simplified CRT. Insight may have been improved by TAU and common non-specific factors such as group meetings and exercises in both conditions, but also be specific elements of both therapies. Since insight is unlikely to improve spontaneously in chronic patients, further research on their underlying mechanisms is needed.

Conflicts of interests

The authors have no conflicts of interest that may have biased their work.

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Contributors

Pijnenborg, Van der Gaag and Aleman developed the intervention and drafted the first version of the manuscript. Pijnenborg, Aleman and Van der Gaag designed the study. Timmerman advised on the statistical analyses. De Vos coordinated the intervention. All authors contributed significantly to the paper.

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